IVAX
Pharmaceuticals, Inc.

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August 30, 2002

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Alphagan (Brimonidine Tartrate) Ophthalmic Solution, 0.2% by Allergan, Inc. has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications. That list, the Approved Drug Products with Therapeutic Equivalence Evaluations, 22nd Edition, referred to as the "Orange Book", contains all FDA-approved drug products. The Orange Book currently lists Alphagan (Brimonidine Tartrate) Ophthalmic Solution, 0.2% in the active section of the list. However, IVAX Pharmaceuticals, Inc. has been advised that marketing of Alphagan (Brimonidine Tartrate) Ophthalmic Solution, 0.2% has been discontinued.

Under the FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drugs application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn, discontinued from marketing or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a

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listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that list drug may be approved {21 CFR 314.161(a)(1)].

As stated, IVAX Pharmaceuticals, Inc. has been advised that Allergan's Alphagan (Brimonidine Tartrate) Ophthalmic Solution, 0.2% was discontinued from marketing. Therefore, it is requested that the FDA determine whether Allergan's Alphagan (Brimonidine Tartrate) Ophthalmic Solution, 0.2% was withdrawn for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided if so requested.

E. Certification

The undersigned certifies that, to their best knowledge and belief, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

IVAX Pharmaceuticals, Inc.

Patricia Jaworski
Associate Director, Regulatory Affairs
New Product Submissions

PJ/GO

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